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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/245,549	02/05/1999	ANTONIS ZERVOS	10287/039001	5009

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 09/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/245,549

Applicant(s)
Zervos

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 20, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-27 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed 6/20/2003 has been entered. Following the entry of the amendment, claims 1 and 3-27 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 3-27^{Jim Z} are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 1, and 3-27 are vague and indefinite because of the phrases "a first common region", "a second common region", "a first region" and "a second region". It is unclear what is the definition for the phrases. Clarification is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1 and 8-10, 13-14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersson et al. (Analytical Biochemistry, 1996, pg. 236, pg. 107-113).

Andersson et al. disclose a novel "double adaptor" strategy for efficient construction of high-quality shotgun libraries. In the method randomly sheared and end-repaired fragments are ligated to oligonucleotide adaptors creating 12 base overhangs. The vector is prepared from a modification M13 vector, by *KpnI/PstI* digestion followed by ligation to oligonucleotide with ends complementary to the overhangs created in the digest. These adaptors create 5'-overhangs complementary to those on the inserts. Following annealing of insert to vector, the DNA is directly used for transformation without a ligation step (See pg. 107, the Abstract). Finally, the method generates a plurality of vector molecules from said plurality of host cells, each vector molecule comprising a different nucleic acid insert molecule. Thereby constructing a DNA library.

Since the claim language recites "a method for constructing a DNA library *in vivo* comprising...", any steps to accomplish the method are allowed to be added into the method. There are no limitations that require to prepare the first region and the second region of the vector, and the first common region and the second common region of the insert, Therefore, the teachings of Andersson et al. anticipate the limitations of claims 1, 8-10, 13-14 and 18.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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5. Claim 27 is rejected under 35 U.S.C. 102(e) as being anticipated by Passmore et al. (5,976,846, issued 11/2/1999).

Passmore et al. disclose the method involving polymerase chain reaction to generate a series of double-stranded DNA fragments. Each fragment contains a region homologous to a portion of the fragment to which it is to be joined. These homologous regions undergo recombination in vivo following transformation into a host with efficient and precise homologous recombination, such as the yeast. The invention also includes kits containing reagents for conducting the method (See the Abstract, fig. 4, fig 6B, column 6, lines 16-67 and column 7, lines 1-16, column 8, lines 33-67). The teachings are inherent that there must be a plurality of primers in the kit. Thus the teachings of Passmore et al. anticipate the limitation of claim 27.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al. (Analytical Biochemistry, 1996, pg. 236, pg. 107-113) as applied to claims 1 and 8-10, 13-14, and 18 above, and further in view of Passmore et al. (5,976,846, issued 11/2/1999).

The teachings of Andersson et al. are set forth in section 4 above. Andersson et al. do not teach that the host cell is a yeast cell.

Passmore et al. disclose the method involving polymerase chain reaction to generate a series of double-stranded DNA fragments. Each fragment contains a region homologous to a portion of the fragment to which it is to be joined. These homologous regions undergo recombination in vivo following transformation into a host with efficient and precise homologous recombination, such as the yeast. The invention also includes kits containing reagents for conducting the method (See the Abstract, fig. 4, fig 6B, column 6, lines 16-67 and column 7, lines 1-16, column 8, lines 33-67).

One of ordinary skill in the art would have been motivated to modify the method of Andersson et al. by applying yeast as host cells. Passmore et al. indicate that the yeast used as a host makes homologous recombination in vivo more efficient and precise. It would have been

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prima facie obvious to apply yeast as host cell to construct a DNA library in vivo via homologous recombination.

Allowable Subject Matter

8. Claims 3-6, and 26 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
9. The references of Li et al. (Nucleic acid research, 1997, Vol. 25(20), pg. 4165-4166), Aslanidis et al. (PCR Methods and Applications, 1994, Vol. 4(3), pg. 172-177) and Tillett et al. (Nucleic acid research, 1999, Vol. 27(19), e26. pg. I-iii) are made of record as references of interests.

Summary

10. No claims are allowable.
11. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.


Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

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12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

^{IT}
August 17, 2003



ETHAN WHISENANT
PRIMARY EXAMINER